*SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4981–5000*

*Adulteration*, Section 501 (a) (1), the article consisted in part of a filthy or decomposed substance; Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling; Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of penicillin, chlortetracycline, or Chloromycetin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

## DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

**4981. Calcium gluconate.** (F. D. C. No. 38639. S. No. 30–305 M.)

QUANTITY: 272 10-cc. ampuls at Chicago, Ill.

SHIPPED: 10–7–55, from Memphis, Tenn. (a return shipment).

LABEL IN PART: (Ampul) "A–50 10 cc. Calcium Gluconate U. S. P. 10% Solution W/V in ampul water no preservative Intramuscular and Intravenous * * * 954."

LIBELED: 10–17–55, N. Dist. Ill.

CHARGE: 502 (j)—the article, when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling of the article, when shipped, namely, "Usual Dose: Adults, intravenous or intra-

muscular. 1 Gram daily or on alternate days; for children, intravenous 0.02 to 0.5 Gram," was dangerous to health because of its pyrogenic effect.

DISPOSITION: 12–16–55. Default—destruction.

**4982. E-Z thumb guard.** (F. D. C. No. 38970. S. No. 27–203 M.)

QUANTITY: 11 display cards, each containing 6 *E-Z thumb guards*, at Phenix City, Ala.

SHIPPED: 12–5–55, from New York, N. Y., by E-Z Products Co.

ACCOMPANYING LABELING: (Display card and card attached to each thumb guard) "E-Z Thumb Guard."

RESULTS OF INVESTIGATION: The device consisted of a piece of metal measuring approximately 1¾ inches in length and 1⅛ inches in width, containing a double row of rectangular perforations and folded so as to form a cylinder and pliable enough to be pressed snugly around the thumb or finger of a baby. Attached to the cylinder was a string long enough to be looped between the fingers and tied around the wrist for securing the thumb guard in place.

LIBELED: 2–27–56, M. Dist. Ala.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that it would prevent thumb or finger sucking; that it would protect the baby's health, teeth, gums, and facial features; that it would guard the baby's teeth; and that it would easily and effectively stop the habit of thumb sucking; and 502 (j)—the article, when used as a baby's thumb guard as suggested in the labeling, would be dangerous to health.

DISPOSITION: 4–2–56. Default—destruction.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**4983. Au-Bi-Ol.** (F. D. C. No. 38873. S. No. 29–944 M.)

QUANTITY: 104 10-cc. vials and 2 100-cc. vials at Brooklyn, N. Y.

SHIPPED: Sometime after 3–29–51, from Hamburg, Germany, by E. Tosse & Co.

LABEL IN PART: (Vial) "Au-Bi-Ol 'Tosse-Germany' 1 cc. contains 0.09 g Bisuthsubsalicylate and 0.005 g Aurothiosalicylate, suspended in vegetable oil * * * Intragluteal * * * E. Tosse & Co., Hamburg."

LIBELED: 12–27–55, E. Dist. N. Y.

CHARGE: 503 (b) (4)—the article, when shipped, was a drug subject to 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2–27–56. Default—destruction.

**4984. Dental hemostat.** (F. D. C. No. 38695. S. No. 22–472 M.)

QUANTITY: 1,386 ¼-oz. btls. at Chicago, Ill.

SHIPPED: 8–3–55, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) "Orylstat For Topical Use Only * * * Active Ingredients: Racemic Epinephrine (dimethylaminoethanolcatechol Hydrochloride) 8%, with chlorobutanol, a chloroform derivative, as a preservative 0.5%, N-(caprylcolaminoformylmethyl)-Pyridinium Chloride* 1:2000. Inert Ingredients: Distilled water, sodium chloride, 90% *Ruson Chloride."